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Dispositif d'aide pour implantation

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus for effectively joining and/or reinforcing separated soft tissues in humans and animals. More particularly, the invention is directed to an apparatus for placement of implants for reapproximating separations in or reinforcing weakened or separated soft tissues normally subject to flexure or strains such as for example, muscles, tendons or ligaments without excessive abrasion.

2. Description of Related Art

Currently, end to end repair of elastic tissue such as muscles, tendons and ligaments, separated either by surgical procedure or injury, involves suturing the ends of the tissue together for a time sufficient to permit normal healing. The ends of the tissue are joined with a wide variety of both absorbable and nonabsorbable suture and implant materials. With nonabsorbable suture materials, the sutures are typically removed within one or two weeks of implantation or left in place.

Conventional curved suture needles, with their small radii, significantly limit the distance over which the suture can be buried. This limitation requires that the sutures be positioned proximal to the severed ends of the tissue. Particularly, in the case of soft elastic tissue such as muscles, tendons or ligaments, conventionally implanted sutures have a tendency to prematurely pull through the joined ends of the tissue when it is flexed or subject to slight strains. When this occurs, the tissue ends separate and healing is arrested necessitating further surgery to repair the damage. One particularly advantageous suture for use in joining ends of soft elastic tissue is a braided suture. Braided sutures are well known in the art and are more supple and workable than conventional monofilament sutures for a given tensile strength. Braided sutures, however, tend to abrade these types of soft tissue as they are implanted. It is desirable to be able to introduce a relatively rough-surfaced braided suture without causing tissue damage because, once in place, this type of suture may provide some frictional resistance to pull-out, keep the two ends of the tissue being reapproximated from pistoning and provide a scaffold for tissue ingrowth as healing progresses thus reinforcing the repair.

It is also common to repair, reinforce or replace tendons and ligaments with prosthetic devices, as for example the anterior cruciate ligament. Prosthetic ligaments such as the Gore-Tex cruciate ligament device are generally implanted through tunnels and anchored at either end. After the tunnels are drilled, it is generally viewed as important to chamfer both the internal and external surfaces to remove sharp edges in an attempt to prevent damage to the prosthesis during placement.

Other common types of procedures involving the reapproximation or reinforcing of tissue ends by implant material include, inter alia, patellar tendon reconstruction, collateral ligament repair, knee repair, rotator cuff, tendon suturing, muscle facia suturing, tendon advancement, reattachment or grafting as well as muscle transfer.

Therefore, it would be highly desirable to have a method and apparatus which permits implant materials of all types to be easily and efficiently positioned in soft or hard tissue over an extended distance remote from ends of the tissue to be joined without excessive abrasion.

Accordingly, it is one object of the present invention to provide an apparatus which facilitates placement of implant materials within soft or hard tissue over extended distances beyond the ends of the tissue to be joined.

It is a further object of the present invention to provide an apparatus which protects the soft or hard tissue and the implant material from abrasion during implantation.

It is another object of the present invention to provide an apparatus for implanting an implant material within soft or hard tissue over extended distances without excessive abrasion to the tissue or implant material.

These and other highly desirable and unusual results are accomplished by the present invention in apparatus for implanting an implant material over extended distances within soft or hard tissue to reapproximate and/or reinforce separated ends of the tissue and thus resist the tendency to prematurely pull through the ends of the reapproximated or reinforced tissues when subject to flexure or slight strain. The apparatus further permit implantation of a wide variety of implant materials such as sutures, including braided sutures, prosthetic devices such as, for example, tapes, ribbons, braided hollow tubes or other elongated structures, in whole or in part, or tissue augmentation devices without excessive abrasion to the tissue or the implant material.

US-A-4392495 discloses passing a flexible tube through bodily tissue and severing it transversely to leave two separate tube lengths in spaced tissue zones. A needle with suture attached is threaded through the tube lengths and the two tube lengths then withdrawn from the tissue to leave the suture embedded in the tissue.

WO 90/03766 discloses apparatus for assisting in the implantation of implant material in accordance with the pre-characterising part of claim 1 below.

SUMMARY OF THE INVENTION

The present invention defined in Claim 1 below, makes available a method and apparatus for facilitating the reapproximation and/or reinforcing of separated ends of soft or hard tissue of human and animal bodies by placement of implant materials to promote healing. The apparatus comprises a cannula with a removable

point releasably attached to one end. The cannula is dimensioned in length, shape and diameter based upon, inter alia, the type of implant material to be implanted, the length of tissue through which the implant material is to pass and the characteristics including shape, of the tissue. For example, in the repair of small tendons or ligaments, a curved cannula approximately 10 cm (4 inches) in length and 16 or 18 gage in diameter would permit the implantation of a stay suture wherein the suture would extend through the tissue defect and emerge on either end approximately 5 cm (2 inches) remote from the defect.

The removable point serves to convert the cannula into a hollow trocar to provide smooth passage of the cannula through the tissue, particularly soft tissue, with minimal damage. Further support and guidance through the tissue may be obtained by providing flutes or grooves longitudinally along the outer body of the cannula adjacent the point.

Once the hollow trocar is in position within the tissue to be approximated or reinforced, the removable point is detached, converting the hollow trocar back into a cannula, open at both ends and ready to guide the implant material. The implant material is advanced through the cannula until it is in position with an end of the implant material extending from either end of the cannula.

Implant material being preattached to the base of the point, when the point is removed the implant material is already in place. When the cannula is removed, the implant material is embedded in the mid-substance of the tissue. The number of implant ends attached to the point can vary from one to any multiple desired for a given procedure, with two ends being preferred. Further, armed sutures (sutures with an attached needle) may be preattached to the removable point by a variety of methods including press fitting, adhesive, or heat shrink tubing. Multiple armed sutures (sutures with more than one attached needle) may be preattached to the point by these methods with the suture material extending into the cannula. These armed sutures include sutures with needles disposed on either one or both ends.

Thereafter, the cannula is withdrawn from the tissue leaving the implant material in place therein to securely approximate and/or reinforce the separated ends of the tissue. Final closure of the edges of the defect may be accomplished by suitable means, e.g., small sutures, if necessary. However, the main implanted suture serves to support and distribute flexure and strain forces applied to the joined tissue to facilitate healing.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, referred to herein and constituting a part hereof, illustrate preferred embodiments of the present invention and, together with the description, serve to explain the principles of the present invention.

FIG. 1 is a side view of one embodiment of the present invention having a substantially linear cannula with removable trocar point.

FIG. 1A is an enlarged side view of one embodiment of the present invention for implanting a braided tubular ligament prosthesis using a linear cannula with the prosthesis attached to a removable taper point.

FIG. 2 is a side view of another embodiment of the present invention having an arcuate cannula with removable cut taper point, wherein the implant material has been omitted.

Fig. 3 is cancelled.

Fig. 3A is a side view of an alternate embodiment of the present invention having the implant material fixed directly to the removable point.

Fig. 3B is cancelled.

Fig. 4 is cancelled.

Figs. 5 and 7 to 10 are perspective views of a tendon repair using apparatus in accordance with the present invention to implant a braided stay suture (Fig. 6 is cancelled).

Fig. 11 is a side view of an embodiment of the present invention having two armed sutures preattached to a removable point.

Fig. 12 is an enlarged view of the removable point of Figure 11.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1, 1A, 2 and 3A show a variety of preferred embodiments of the apparatus in accordance with the present invention. Fig. 1 represents a substantially linear cannula 20 having a removable point 22 detachably positioned in a proximal end 24 of a linear cannula 20. Removable point 22 is press fit with a slight interference into proximal end 24 to facilitate secure attachment and easy removal.

One skilled in the art, however, would recognise that any releasable attachment means would be appropriate including, threading, twist on or breakaway lines. For example, the entire assembly can be formed as a single unit with a preformed breakaway line to enable the point to be broken off after positioning, leaving the cannula in place. This assembly can be formed using known techniques such as, for example, extrusion, molding, etc. Appropriate materials include, stiff or reinforced plastics, aluminium, stainless steel, etc.

The breakaway point of such an embodiment can be the shape of a flattened cone with sharp edges. Further, flutes can be provided longitudinally along the cannula to aid and guide the assembly through the tissue.

Point 22 is formed in the shape of a trocar to ease entry into soft tissue. Other shapes and configurations are also useful including: conical, both convex and concave; arcuate conical; tapered; reverse cutting; side cutting; and flattened conical with a plurality of sharpened edges. In order to ease entry of the cannula into the tissue, the points are dimensioned at their base to have

approximately the same diameter as the cannula to which they are attached.

Cannula 20 is dimensioned based on the particular application and the type of approximating or reinforcing material to be implanted. For example, in hand tendon repair, cannulas of 16 or 18 gage diameter in varying lengths are particularly useful for implanting suture material to join separated ends. For other applications such as larger tendons, muscle, soft tissue or ligament repair, size, shape, length and diameter may be varied as required.

FIG. 1A discloses an alternate embodiment of the present invention for implanting a braided tubular ligament prosthesis 21. A substantially linear cannula 23 encloses a portion of the prosthesis 21, one end of which is fixed directly to removable taper point 25. This point 25 is press fit in a similar manner to that described above with respect to the embodiment of FIG. 1.

FIG. 2 shows a substantially arcuate cannula 26 having a removable point 28 which is releasably attachable to a proximal end 30 of cannula 26. In this embodiment, point 28 is provided with internal threads 32 which are threadably engagable with external threads 34 formed on proximal end 30 of cannula 26. Alternatively, annular rings and grooves could be substituted for threads 32, 34 such that point 28 interfits over cannula 26.

A cannula 36 having a partially linear and partially arcuate shape is shown in Fig. 3A. This embodiment of the present invention also includes a removable point 38 which is formed in the shape of an arcuate cone following the curve of cannula 36.

An implant material such as, for example, a braided suture 41, may be fixed directly to removable point 38 as shown in Fig. 3A. This configuration would serve to pull the braided suture 41 directly into position simply by removing point 38.

Figs. 5, 7-10 illustrate the use of one embodiment of the present implant assist apparatus to repair a defect in a tendon using a braided type stay suture. Fig. 5 shows the tendon, generally 56, separated into a first end 58 proximate muscle tissue 60 and a second end 62 proximate the bone (not shown).

Referring now to Fig. 7, implant assist apparatus 64, as shown disassembled in Fig. 3A, is used to implant the braided stay suture 66 starting at the muscle tissue 60, through first and second ends, 58 and 62, respectively, to emerge from tendons 56 remote from second end 62.

The implant assist apparatus 64 is passed into tissue across the site which is being repaired. Point 38 is inserted into muscle tissue 60 at location 68 remote from first tendon end 58. The apparatus 64 is guided through the tissue, passing through both first and second tendon ends, 58 and 62 respectively (Figure 7), until point 38 emerges from the tendon at exit site 70 (Figure 8). At this stage, distal end 44 of cannula 36 should be exposed at entry location 68 and point 38 should extend out of exit location 70 a distance sufficient to expose proximal end 41 of cannula 36. See FIG. 8.

While holding cannula 36 near the exposed distal end 44, point 38 is detached until suture 66 is visible. Suture 66 is then pulled carefully until approximately equal lengths are exposed from proximal and distal ends of cannula 36. By gripping one end of suture 66 (in this case the end extending from exit location 70) cannula 36 is pulled out of entry location 68 in the direction of arrow 72 leaving the suture 66 in position. See FIG. 9.

The ends of suture 66 are then tied off, preferably using oblong tying buttons 74 as shown in FIG. 10, to close the ends of the tendon defect to promote healing. Where desired, whipping sutures 76 may be used to close any unsatisfied ends of the tendon 56. Also, surgical needles may be attached to the free ends of the exposed suture and additional suturing and tying may be performed to fully anchor the suture and complete the repair.

Referring to FIG. 11, there is shown an embodiment of the present invention wherein a pair of double armed sutures (i.e. sutures with a needle at both ends), shown generally at 80, extend through cannula 88 and are preattached to removable point 82. As shown, the cannula 88 is arcuate, however, alternately the cannula 88 can be linear as in Figure 1. In this particular embodiment, two straight needles 86 are releasably preattached to point 82 by means of heat shrink tubing 84. The cannula is therefore dimensioned to have an inside diameter of sufficient size to receive adjacently aligned needles enveloped by shrink tubing. As shown in Figure 12, heat shrink tubing 84 fits around narrowed portion 83 of point 82 and tightly engages flange 85.

Suture material 90 extends through proximal opening 92 into cannula 88 and has a second pair of needles 94 attached to distal ends thereof. In this particular embodiment shown in the drawings, straight needles are used on both the proximal and distal ends of suture material 90. However, one skilled in the art will appreciate that a wide variety of needle types and shapes may be substituted.

In operation, after the pair of needles 86 are releasably preattached to removable point 82 by heat shrink tubing 84, the removable point 82 is removably inserted into the proximal opening 92 of cannula 88 as described above with respect to other embodiments. The suture material may be dimensioned such that the distal end thereof is retained within cannula 88 or alternatively may extend outside the distal opening 96 as shown in Figure 11. After the cannula is emplaced within the subject tissue in the manner described above, removable point 82 is separated from the proximal opening 92 of cannula 88 exposing needles 86. These needles are then separated from the heat shrink tubing 84 on removable point 82 (e.g. by pulling them out of the end of the tubing). The cannula 88 may be withdrawn from the tissue in a distal direction leaving the pair of sutures 80 with attached needles in place to be used in the surgical procedure to be performed. This embodiment is

particularly useful in procedures wherein multiple sutures with attached needles must be passed through tissue in close proximity to effect joining or repair.

Claims

1. Apparatus for assisting in the implantation of implant material in tissue to be reapproximated or reinforced comprising:

   cannula means (36) having a hollow body, an open distal end (44) and a proximal end (24) which in use becomes open, said cannula dimensioned to receive the implant material;
   point means (38) detachably protruding from the proximal end of the cannula means for penetrating tissue;

   and **characterised in that:**
   said implant material is preattached through said cannula to said point means; and
   said point means is releasably mounted to the open proximal end of the cannula means.

2. Apparatus as claimed in claim 1 wherein said cannula means is linear in shape, arcuate in shape of partially linear and partially arcuate in shape.

3. Apparatus as claimed in claim 1, wherein said implant material is selected from sutures, prosthetic devices and tissue augmentation devices.

4. Apparatus as claimed in claim 3 wherein said implant material comprises a braided suture (41).

5. An implant assist apparatus as in claim 3 or 4 wherein said implant material comprises at least one needle (86) attached to a suture.

6. Apparatus as in claim 5, and comprising at least one needle attached to each end of said suture.

7. Apparatus as claimed in claim 5 or 6 wherein said needle is releasably attached to said point means by heat shrink tubing (84).

8. Apparatus as claimed in any one of the preceding claims wherein said cannula further comprises at least one flute formed longitudinally therein.

9. Apparatus as claimed in any one of the preceding claims, wherein said point means is formed in the shape of a trocar or an arcuate cone.

10. Apparatus as claimed in any one of the preceding claims, wherein said point means is formed integrally with said cannula and is detachable therefrom.

11. Apparatus as claimed in any one of the preceding claims, wherein a pair of sutures extend side by side through said cannula, each suture having a needle attached to both ends.

Patentansprüche

1. Vorrichtung zum Unterstützen des Implantierens eines Implantatmaterials in Gewebe, das wieder angenähert oder verstärkt werden soll, umfassend:

   Kanülenmittel (36) mit einem hohlen Körper, einem offenen distalen Ende (44) und einem proximalen Ende (24), das bei der Verwendung offen wird, wobei die Kanüle dimensioniert ist, um das Implantatmaterial aufzunehmen;
   Spitzenmittel (38), das abnehmbar vom proximalen Ende des Kanülenmittels hervorsteht, um Gewebe zu durchdringen;

   und **dadurch gekennzeichnet, daß**
   das Implantatmaterial durch die Kanüle an dem Spitzenmittel vorbefestigt ist; und
   das Spitzenmittel lösbar an dem offenen proximalen Ende des Kanülenmittels befestigt ist.

2. Vorrichtung gemäß Anspruch 1, worin das Kanülenmittel eine geradlinige Form, bogenförmige Form oder teilweise geradlinige und teilweise bogenförmige Form besitzt.

3. Vorrichtung gemäß Anspruch 1, worin das Implantatmaterial von Nahtmaterialien, protetischen Einrichtungen und Gewebevermehrungseinrichtungen ausgewählt wird.

4. Vorrichtung gemäß Anspruch 3, worin das Implantatmaterial ein geflochtenes Nahtmaterial (41) umfaßt.

5. Implantathilfsvorrichtung gemäß Anspruch 3 oder 4, worin das Implantatmaterial zumindest eine Nadel (86) umfaßt, die an einem Nahtmaterial angebracht ist.

6. Vorrichtung gemäß Anspruch 5, umfassend zumindest eine Nadel, die an jedem Ende des Nahtmaterials angebracht ist.

7. Vorrichtung gemäß Anspruch 5 oder 6, worin die Nadel lösbar an dem Spitzenmittel durch eine Wärmeschrumpfröhre (84) angebracht ist.

8. Vorrichtung gemäß einem der vorhergehenden Ansprüche, worin die Kanüle weiter umfaßt zumindest eine Hohlkehle, die in Längsrichtung darin gebildet ist.

9. Vorrichtung gemäß einem der vorhergehenden

Ansprüche, worin das Spitzenmittel in der Form eines Trokars oder eines bogenförmigen Kegels gebildet ist.

10. Vorrichtung gemäß einem der vorhergehenden Ansprüche, worin das Spitzenmittel einstückig mit der Kanüle gebildet ist und von dieser lösbar ist.

11. Vorrichtung gemäß einem der vorhergehenden Ansprüche, worin ein Paar von Nahtmaterialien sich Seite an Seite durch die Kanüle erstreckt, wobei jedes Nahtmaterial eine Nadel an beiden Enden angebracht besitzt.

Revendications

1. Appareil pour assister l'implantation d'un matériau d'implant dans du tissu à rapprocher ou à renforcer comportant :

   un moyen de c annule (36) avec un corps creux, une extrémité distale ouverte (44) et une extrémité proximale (24) qui, en cours d'utilisation s'ouvrira, ladite cannule étant dimensionnée pour recevoir le matériau d'implant;
   un moyen de pointe (38) dépassant détachablement de l'extrémité proximale du moyen de cannule pour pénétrer dans le tissu;

   et **caractérisé en ce que** :
   ledit matériau d'implant est attaché préalablement à travers ladite cannule audit moyen de pointe; et
   ledit moyen de pointe est monté relâchablement à l'extrémité proximale ouverte du moyen de cannule.

2. Appareil selon la revendication 1, dans lequel ledit moyen de cannule a une forme linéaire, une forme arquée, une forme partiellement linéaire et partiellement arquée.

3. Appareil selon la revendication 1, dans lequel ledit matériau d'implant est choisi parmi les sutures, des dispositifs de prothèse et des dispositifs d'augmentation de tissu.

4. Appareil selon la revendication 3, dans lequel ledit matériau d'implant comprend une suture tressée (41).

5. Appareil assistant l'implant selon les revendications 3 ou 4, dans lequel ledit matériau d'implant comprend au moins une aiguille (86) attachée à une suture.

6. Appareil selon la revendication 5, et comportant au moins une aiguille attachée à chaque extrémité de ladite suture.

7. Appareil selon la revendication 5 ou 6, dans lequel ladite aiguille est fixée relâchablement audit moyen de pointe par un tube thermorétractable (84).

8. Appareil selon l'une des revendications précédentes, dans lequel ladite cannule comporte en outre au moins une nervure formée longitudinalement dans celle-ci.

9. Appareil selon l'une des revendications précédentes, dans lequel ledit moyen de pointe est réalisé sous la forme d'un trocart ou d'un cône arqué.

10. Appareil selon l'une des revendications précédentes, dans lequel ledit moyen de pointe est réalisé intégralement avec ladite cannule et est détachable de celle-ci.

11. Appareil selon l'une des revendications précédentes, dans lequel une paire de sutures s'étend côte à côte à travers ladite cannule, chaque suture ayant une aiguille attachée aux deux extrémités.

Fig.1

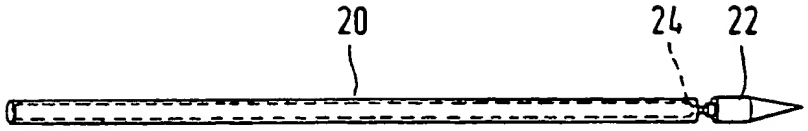


Fig.1A

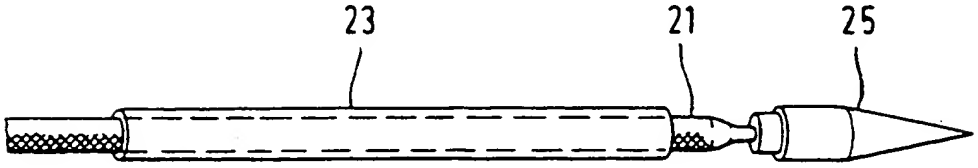


Fig.2

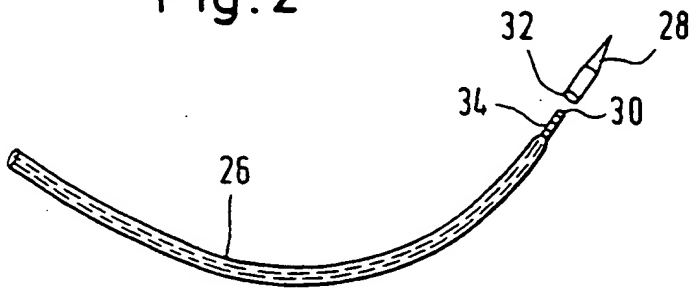


Fig.3A

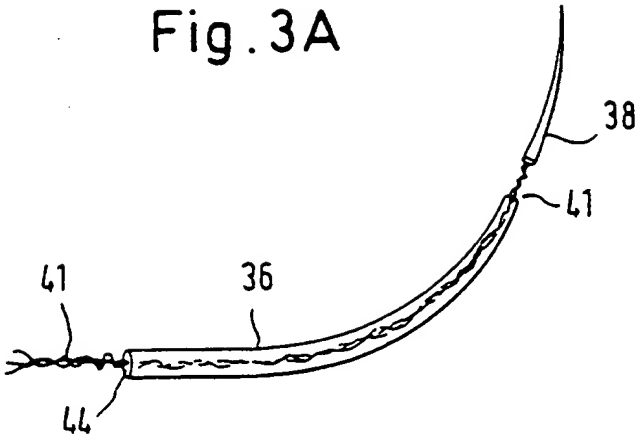


Fig.5

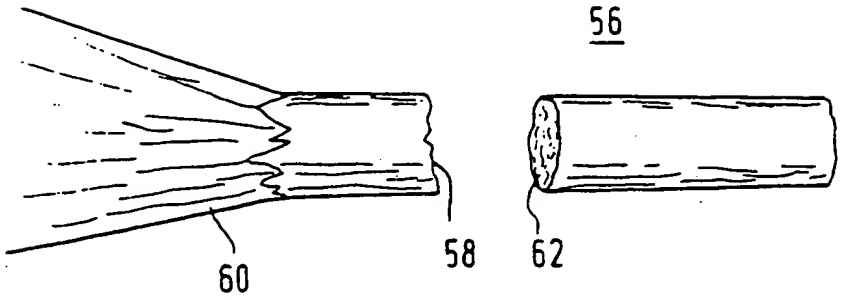


Fig.7

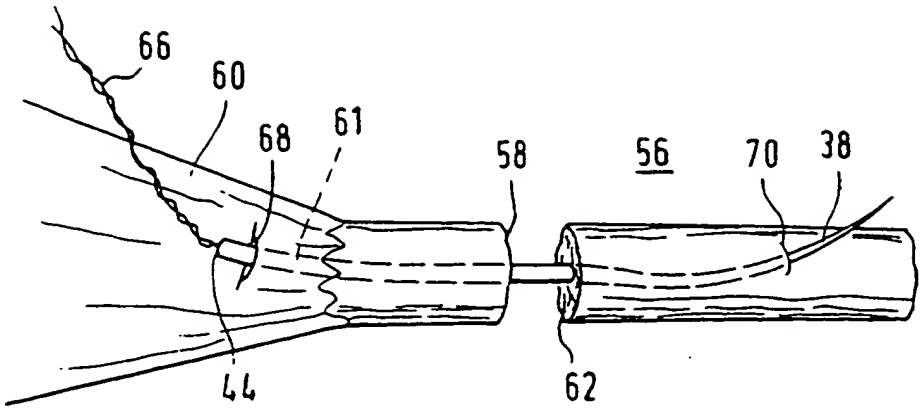


Fig.8

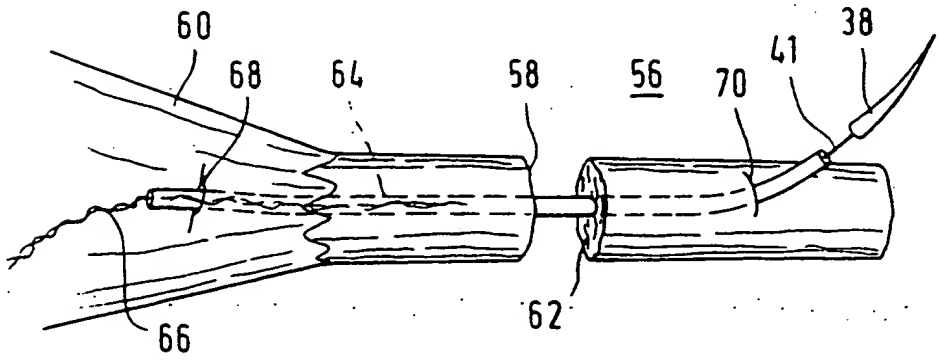


Fig. 9

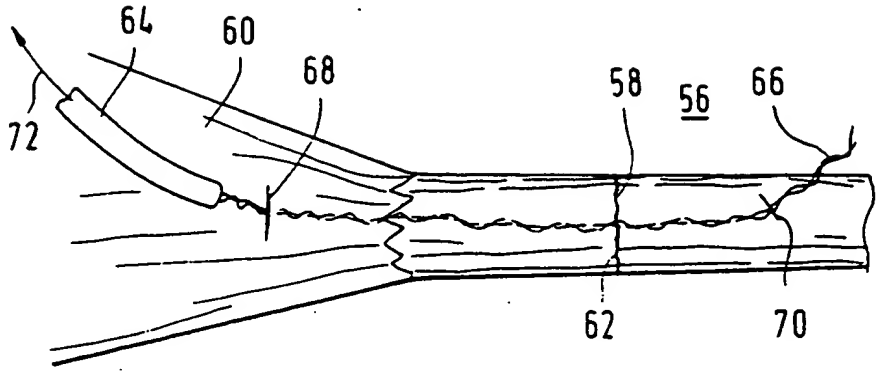
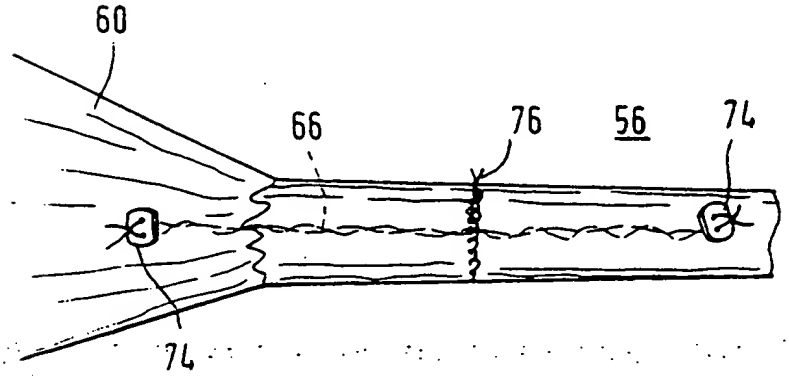


Fig. 10



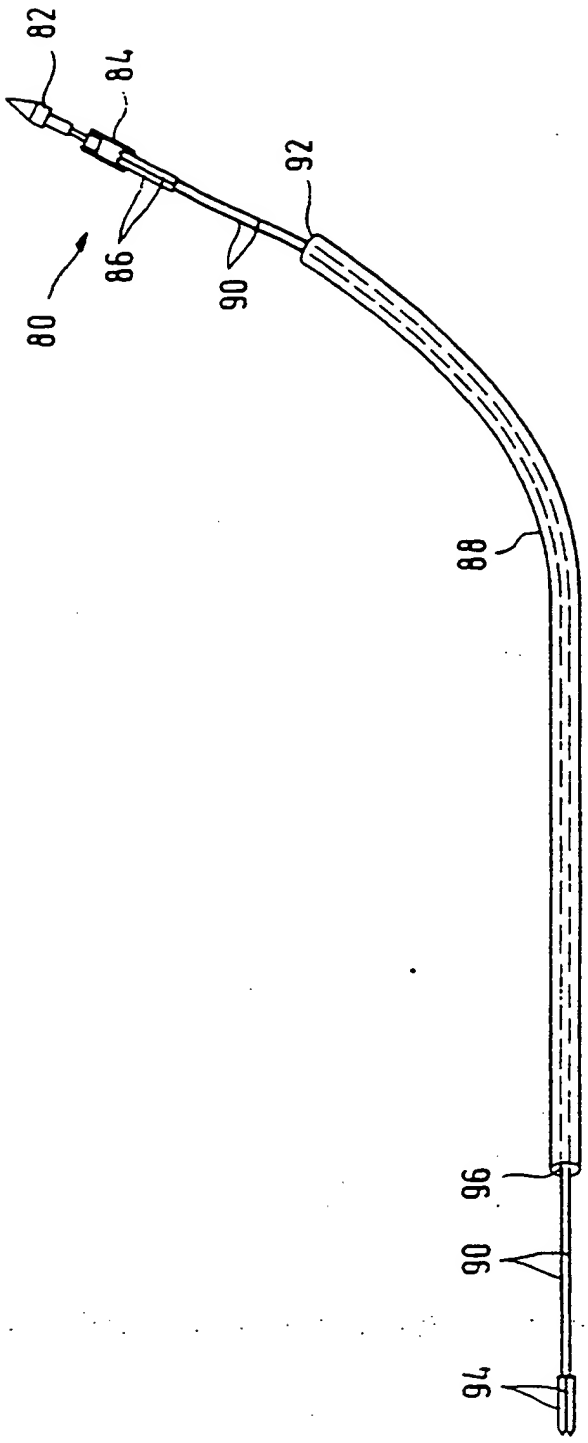


Fig.11

Fig. 12